

REMARKS

1. Upon further consideration, Applicant has elected not to pursue the Notice of Appeal filed on April 21, 2008 and, instead, requests that examination of the application be reopened. The following is a response to the nonfinal office action mailed on October 16, 2007.

2. Following is a summary of the rejections in the Office Action:

Claims 1-4, 20, 24, 67-71 and 73-75 were rejected under 35 USC 102(b) as anticipated by Barken (US 5531742).

Claims 6 and 7 were rejected under 35 USC 103(a) as unpatentable over Barken (US 5531742) in view of Thomas III et al (US 4911170).

Claim 8 was rejected under 35 USC 103(a) as unpatentable over Barken (US 5531742) in view of Bernstein (US 6132699).

Claim 10 was rejected under 35 USC 103(a) as unpatentable over Barken (US 5531742) in view of LeBlanc (US 5989189).

Claim 18 was rejected under 35 USC 103(a) as unpatentable over Barken (US 5531742) in view of Schachar (US 5989189).

Claims 19, 27-29, 31 and 46 were rejected under 35 USC 103(a) as unpatentable over Barken (US 5531742) in view of Steen et al (US 5984904).

Claim 21 was rejected under 35 USC 103(a) as unpatentable over Barken (US 5531742).

Claims 22 and 23 were rejected under 35 USC 103(a) as unpatentable over Barken (US 5531742) in view of Imling et al (US 6203499).

Claim 25 was rejected under 35 USC 103(a) as unpatentable over Barken (US 5531742) in view of Simon (US 4883053).

Claim 26 was rejected under 35 USC 103(a) as unpatentable over Barken (US 5531742) in view of Mohr, Jr. et al (US 5921954).

Claims 32-34, 37, 38, 45 and 72 were rejected under 35 USC 103(a) as unpatentable over Barken (US 5531742) in view of Lynch et al (US 6524275).

Claims 39 and 42 were rejected under 35 USC 103(a) as unpatentable over Barken (US 5531742) in view of Lafont et al (US 5957975).

3. The pending claims 1-77 have been canceled and replaced with new claims 78-141. The new claims correspond to the elected species of the invention, with the exception of dependent claims 96-110 and 129-134, which correspond with previously withdrawn claims. These unelected claims have been retained so that they can be entered upon allowance of a generic base claim.

REJECTIONS UNDER 35 USC 102

4. Base claim 78 clearly distinguishes Barken by the novel features of:

“a surgical access device physically coupled to the locating device for guiding the microsurgical device in relation to the locating device the surgical access device being configured to access Schlemm's Canal within the imaging plane of the locating device and to deliver the microsurgical device into Schlemm's Canal along a path spaced apart distally from the tissue contacting surface of the locating device and approximately parallel to the tissue contacting surface of the locating device.”

Barken does not disclose an apparatus where a surgical access device is physically coupled to a locating device, and in particular Barken does not disclose an apparatus where a microsurgical device is delivered along a path spaced apart distally from a tissue

contacting surface of the locating device and approximately parallel to the tissue contacting surface of the locating device.

Claim 78 is therefore submitted as being patentable over Barken under 35 USC 102.

Claims 79-110, being dependent on claim 78, are also submitted as being patentable over Barken under 35 USC 102 by recitation of these same novel features.

5. Base claim 111 clearly distinguishes Barken by the novel combination of:

“the locating device being coupled to the handle such that the tissue contacting surface is approximately perpendicular to the longitudinal axis of the handle, the locating device adapted for non-invasively locating Schlemm's Canal within the patient's eye and for indicating when Schlemm's Canal is located in a imaging plane that extends distally from the tissue contacting surface of the locating device;”

and

“a surgical access device physically coupled to the locating device for guiding the microsurgical device in relation to the locating device, the surgical access device being configured to access Schlemm's Canal within the imaging plane of the locating device and to deliver the microsurgical device into Schlemm's Canal along a path spaced apart distally from the tissue contacting surface of the locating device and approximately perpendicular to the longitudinal axis of the handle of the apparatus.”

Barken does not disclose an apparatus where a locating device is coupled approximately perpendicular to the longitudinal axis of a handle, and a surgical access device is physically coupled to the locating device such that a microsurgical device is delivered along a path spaced apart distally from the tissue contacting surface of the locating device and approximately perpendicular to the longitudinal axis of the handle of the apparatus.

Claim 111 is therefore submitted as being patentable over Barken under 35 USC 102.

Claims 112-134, being dependent on claim 111, are also submitted as being patentable over Barken under 35 USC 102 by recitation of these same novel features.

6. Base claim 135 clearly distinguishes Barken by the novel features of:

“a surgical access device physically coupled to the locating device for guiding the microsurgical device in relation to the locating device, the surgical access device having a cantilever beam that extends axially with respect to the tissue contacting surface of the locating device, a guiding sleeve coupled to the cantilever beam, an angle adjustment mechanism for adjusting an angle of the guiding sleeve with respect to the tissue contacting surface of the locating device and a mechanism for advancing the microsurgical device through the guiding sleeve and into Schlemm's Canal within the patient's eye.”

Barken does not disclose an apparatus where a surgical access device is physically coupled to a locating device, and in particular Barken does not disclose an apparatus where the surgical access device has a cantilever beam that extends axially from the tissue contacting surface of the locating device, a guiding sleeve coupled to the cantilever beam, an angle adjustment mechanism for adjusting an angle of the guiding sleeve with respect to the tissue contacting surface of the locating device and a mechanism for advancing the microsurgical device.

Claim 135 is therefore submitted as being patentable over Barken under 35 USC 102. Claims 136-141, being dependent on claim 135, are also submitted as being patentable over Barken under 35 USC 102 by recitation of these same novel features.

REJECTIONS UNDER 35 USC 103

4. The previous claims were rejected under 35 USC 103 on the basis of Barken (US 5531742) separately and in combination with various references, including Thomas III et al (US 4911170), Bernstein (US 6132699), LeBlanc (US 5989189), Schachar (US 5989189), Steen et al (US 5984904), Imling et al (US 6203499), Simon (US 4883053), Mohr, Jr. et al (US 5921954), Lynch et al (US 6524275) and Lafont et al (US 5957975).

However, Applicant submits that the new claims overcome these rejections. In particular, it would not have been obvious to modify Barken to include the novel features of base claims 78, 111 and 135 that are discussed above. These novel features are particular to the unique geometry of the eye and the location of Schlemm's Canal within the eye. In humans and other primates, Schlemm's Canal runs parallel to and approximately 1 mm beneath the scleral surface of the eye. When using a contact imaging device, such as an ultrasound transducer, to locate Schlemm's Canal for insertion of a microsurgical device, it is necessary to direct the microsurgical device along a path spaced apart distally from the tissue contacting surface of the locating device and approximately parallel to the tissue contacting surface of the imaging device. This feature is recited explicitly in claim 78, whereas claims 111 and 135 recite different physical configurations of the surgical access device that are used to achieve the necessary geometrical relationship between the locating device and the microsurgical device.

Barken does not include any structure that would result in the necessary geometrical relationship between the locating device and the microsurgical device for locating Schlemm's Canal within the eye and directing a microsurgical device into it. Furthermore, it would not be obvious to one of ordinary skill in the art to modify Barken to meet the claim limitations. Barken discloses a cryosurgical system that is particularly adapted for cryosurgery of the prostate gland. The geometry of the cryosurgical system of Barken is completely unsuitable for accessing Schlemm's Canal within a patient's eye. On the other hand, modifying the cryosurgical system to have the geometry necessary for accessing Schlemm's Canal within the eye would render the cryosurgical system unsuitable for surgery of the prostate gland. MPEP 2143.01 (V) specifically states: "If [the] proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification." *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984) Thus, it would not be obvious to modify the cryosurgical system of Barken to meet the limitations of the claims.

Considering the other cited references:

Thomas III et al (US 4911170) discloses a high frequency focused ultrasound transducer for invasive tissue characterization. However, Thomas contains no teachings related to a surgical access device physically coupled to the ultrasound transducer for guiding a microsurgical device in relation to the ultrasound transducer, much less the specific device geometries claimed by Applicant. Given that neither Barken nor Thomas discloses these features, no possible combination of the references could result in Applicant's claimed invention.

Bernstein (US 6132699) discloses microencapsulated fluorinated gases for use as imaging agents. However, Bernstein contains no teachings related to a surgical access device physically coupled to a locating device for guiding a microsurgical device in relation to the locating device, much less the specific device geometries claimed by Applicant. Given that neither Barken nor Bernstein discloses these features, no possible combination of the references could result in Applicant's claimed invention.

LeBlanc (US 5989189) discloses an ultrasound imaging system for ophthalmic imaging. However, LeBlanc contains no teachings related to a surgical access device physically coupled to the ultrasound transducer for guiding a microsurgical device in relation to the ultrasound transducer, much less the specific device geometries claimed by Applicant. Given that neither Barken nor LeBlanc discloses these features, no possible combination of the references could result in Applicant's claimed invention.

Schachar (US 5989189) discloses a device for treatment of macular degeneration and other eye disorders. Examiner cited Schachar, column 9, lines 53-56, as teaching a device with a curvature that conforms to the curvature of the patient's eye. However, Examiner has taken this feature out of its proper context. Reading the sentences before and after the one cited by Examiner makes it clear that the device of Schachar is intended to *modify the shape of the eye*, not to conform to it:

The exemplary segment body has a *prescribed shape capable of exerting a force to the eye 100* once associated therewith, *that modifies the shape of the eye 100* to manipulate the retinal area 215 and, possibly, to alter the distance between the

lens 130 and the retina 140. In the present embodiment, the exemplary prescribed shape is curved, and the curvature is chosen to provide at least an approximate match for the curvature of the surface of the eye, or, in alternate embodiments (e.g., FIG. 8), the curvature is chosen to provide at least an approximate match for the curvature of any adjacent device bodies also associated with the eye. As will be described with reference to FIGS. 10 and 11, the segment body has the inner surface 312 and an outer surface (not shown) that are separated sufficiently to suitably *modify the shape of the eye by exerting the force* with respect thereto.

Given that Schachar teaches a device that is intended for modifying the shape of the eye, and particularly since the device is intended to be implanted in contact with the retina at the *back* of the eye (see FIG. 2), it would not have been obvious to one of ordinary skill in the art to combine Schachar with Barken, as suggested by Examiner.

In addition, Schachar contains no teachings related to a surgical access device physically coupled to a locating device for guiding a microsurgical device in relation to the locating device, much less the specific device geometries claimed by Applicant. Given that neither Barken nor Schachar discloses these features, no possible combination of the references could result in Applicant's claimed invention.

Steen et al (US 5984904) discloses a sleeve for a surgical instrument having internal protuberances for allowing fluid flow through the sleeve even when a cannula is inserted through the sleeve. Applicant notes that the protuberances do not constitute a raised ridge, nor are they on a tissue contacting surface of the device, nor are they associated with a locating or imaging device at all. Given that the protuberances are for allowing fluid flow through the lumen of the sleeve, not for retaining a reservoir of fluid on a tissue contacting surface of a device, it would not have been obvious to one of ordinary skill in the art to combine Steen with Barken, as suggested by Examiner.

In addition, Steen contains no teachings related to any means to physically couple the sleeve to a locating device for guiding a microsurgical device in relation to the locating device, much less the specific device geometries claimed by Applicant. Given that neither Barken nor Steen discloses these features, no possible combination of the references could result in Applicant's claimed invention.

Imling et al (US 6203499) discloses a multiple angle needle guide to facilitate ultrasound guided biopsies. Applicant notes that the needle guide 10 of Imling does not constrain the angle of the needle 22 at all; the biopsy needle 22 can be freely moved within the large slot 44 and repositioned at any angle. The only constraint is that the slot 44 keeps the needle 22 within the scan plane of the ultrasound imaging probe 12 when it is inserted. (See FIG. 2c and column 5, lines 17-27.) This arrangement would be nearly useless for guiding a microsurgical instrument into Schlemm's Canal within the patient's eye. Consequently, it would not have been obvious, or even beneficial, to combine Imling with Barken, as suggested by Examiner.

Furthermore, Imling does not disclose any structure suitable for delivering a microsurgical device into Schlemm's Canal along a path spaced apart distally from the tissue contacting surface of the locating device and approximately parallel to the tissue contacting surface of the locating device. Given that neither Barken nor Imling discloses these features, no possible combination of the references could result in Applicant's claimed invention.

Simon (US 4883053) discloses a self-supporting angulator device for precise percutaneous insertion of a needle or the like. Given that a primary function of the device is to be self-supporting and attachable to the skin of the patient and that it includes no means for physically coupling the device to a locating device, it would not have been obvious to one of ordinary skill in the art to combine Simon with Barken to make the claimed invention. Furthermore, since neither Barken nor Simon discloses this feature, no possible combination of the references could result in Applicant's claimed invention.

Mohr, Jr. et al (US 5921954) discloses a system for treating aneurysms by applying hardening/softening agents to hardenable/softenable substances. However, Mohr contains no teachings related to a surgical access device physically coupled to a locating device for guiding a microsurgical device in relation to the locating device, much less the specific device geometries claimed by Applicant. Given that neither Barken nor Mohr discloses these features, no possible combination of the references could result in Applicant's claimed invention.

Lynch et al (US 6524275) discloses an inflatable device and method for treating glaucoma. However, Lynch contains no teachings related to a surgical access device physically coupled to a locating device for guiding the inflatable device in relation to the locating device and into Schlemm's Canal. Lynch also does not disclose any of the specific device geometries of a surgical access device that are claimed by Applicant. Given that neither Barken nor Lynch discloses these features, no possible combination of the references could result in Applicant's claimed invention.

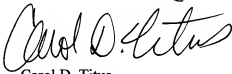
Lafont et al (US 5957975) discloses a stent having a programmed pattern of in vivo degradation. However, Lafont contains no teachings related to a surgical access device physically coupled to a locating device for guiding a microsurgical device in relation to the locating device, much less the specific device geometries claimed by Applicant. Given that neither Barken nor Lafont discloses these features, no possible combination of the references could result in Applicant's claimed invention.

CONCLUSION

For all the reasons above, Applicant submits that the claims all define novel subject matter that is nonobvious. Therefore, allowance of these claims is submitted to be proper and is respectfully requested.

Applicant invites the Examiner to contact Applicant's representative as listed below for a telephonic interview if so doing would expedite the prosecution of the application.

Very respectfully submitted,



Carol D. Titus
GSS Law Group
3900 Newpark Mall Rd
Third Floor, Suite 317
Newark, CA 94560

Reg. No. 38,436
Phone (510) 742-7417
Fax (510) 742-7419